

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

FORM APPROVED
OMB NO 0579-0036

1 with USDA

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS
include Z:

22-R-0001, Cust Id 158

(b)(6) (b)(7)(C)

BELL LABS LUCENT TECHNOLOGIES

600 MOUNTAIN AVENUE

P. O. BOX 636

MURRAY HILL, NJ 07974

DEC - 5 2000

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

Bell Laboratories, Lucent Technologies

600 Mountain Ave. Rm 1C-423, Murray Hill, NJ 07974

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Animals					
Zebra Fish	100	0	100	0	100
Slugs	500	0	500	0	500
Rats	20	0	200	0	200
Zebra Finch	10	0	100	0	100
Gold Fish	20	0	200	0	200

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTES RESEARCH FACILITY OFFICIAL

SIGNATURE

DATE SIGNED

11/30/00

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

SEP 26 2000

1. REGISTRATION NO.

FORM APPROVED
OMB NO. 0579-0036

red with USDA

2. HEADC 22-R-0005, Cust Id 8203
include

(b)(6), (b)(7)(C)

N J STATE DEPT OF HEALTH
CN 360
TRENTON, NJ 08625

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

Laboratory Bldg. - PH&EL

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

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- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTES RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF

10

DATE SIGNED

9-21-00

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

22-R-0013

FORM APPROVED
OMB NO 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTER

include Zip 22-R-0013, Cust Id 163

with USDA

WORLDWIDE MOBILE VETERINARY UNIT
8 FOX HUNT DRIVE
ROCKAWAY, NJ 07866

DEC - 5 1990

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs			52		52
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTES RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 USC Section 2143)

SIGNATURE OF CEO OR INSTITUTIONAL OFFICIAL

DATE SIGNED

12-1-90

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT) B

10/1/99 - 9/30/00

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA)

Include:

22-R-0014, Cust Id 164

NOVARTIS CORPORATION
PHARMACEUTICALS DIVISION
556 MORRIS AVENUE
SUMMIT, NJ 07901

Attach additional

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, less sheets if necessary.)

FACILITY LOCATIONS (Sites)

Buildings 130 & 133

556 Morris Avenue
Summit, NJ 07901

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	-	24	32	-	56
5. Cats	-	-	-	-	-
6. Guinea Pigs	-	29	29	-	58
7. Hamsters	-	-	189	-	189
8. Rabbits	-	186	839	-	1025
9. Non-human Primates	2	12	84	-	98
10. Sheep	-	-	-	-	-
11. Pigs	-	-	39	-	39
12. Other Farm Animals	-	-	-	-	-
Goats	-	-	20	-	20
13. Other Animals					-

ASSURANCE STATEMENTS

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- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL.
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Sec. 1601-1643)

DATE SIGNED

11/2/00

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

FORM APPROVED
OMB NO 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address as registered with USDA, include Zip

22-R-0016, Cust Id 174

JOHNSON & JOHNSON CONSUMER PRODUCTS, INC.
RESEARCH & DEVELOPMENT
199 GRANDVIEW ROAD
SKILLMAN, NJ 08558

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

Johnson & Johnson
Consumer Products Worldwide
Skillman, New Jersey

Barton West End Facilities
Oxford, New Jersey

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs					0
5. Cats					0
6. Guinea Pigs		376	178		554
7. Hamsters		290			290
8. Rabbits		348			348
9. Non-human Primates					0
10. Sheep					0
11. Pigs			133*		133
12. Other Farm Animals					0
13. Other Animals					0
*Two pigs were housed at Barton's West End Facilities.					

ASSURANCE STATEMENTS

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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

11/10/00

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

22-R-0020

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

DEC 1 2000

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)
University of Medicine & Dentistry
185 South Orange Avenue
MSB A-604
Newark NJ 07103-2714
status: Active

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs		41			41
5. Cats		82			82
6. Guinea Pigs		14			14
7. Hamsters		205			205
8. Rabbits		157			157
9. Non-human Primates					
10. Sheep					
11. Pigs		94			94
12. Other Farm Animals					
13. Other Animals					
Gerbils		19			19
S.A. Opossums		20			20

ASSURANCE STATEMENTS

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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 USC Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME OF C.E.O. OR INSTITUTIONAL OFFICIAL

DATE SIGNED

11/30/00

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

FORM APPROVED
OMB NO 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY

include 22-R-0012, Cust Id 172

Shared with USDA

ETHICON, INC.
P.O. BOX 151
SOMERVILLE, NJ 08876

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

ETHICON, INC.
P.O. Box 151

SOMERVILLE, NJ 08876

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A Animals Covered By The Animal Welfare Regulations	B Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes	C Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs	D Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs	1		21*		21
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits			94*		94
9. Non-human Primates					
10. Sheep			6*		6
11. Pigs			430*		430
12. Other Farm Animals					
Goat	3		43*		43
13. Other Animals					
Note:	4 Dogs,	3 Rabbits,	6 Sheep,	10 Goats & 416 Pigs were involved	
	were involved	in terminal	operative	procedures.	

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 USC Section 2143)

DATE SIGNED

11/30/00

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

FORM APPROVED
OMB NO. 0579-0036

**ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)**

2. HEADQUARTERS RESEARCH FACILITY (Name and Address - include Zip Code) - must be approved with USDA

22-R-0028, Cust Id 168

BRISTOL-MYERS SQUIBB COMPANY
P.O. BOX 4000
PRINCETON, NJ 08543

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, sheets if necessary)

For these purposes. Attach additional

FACILITY LOCATIONS (Sites)

Somerville, New Jersey

Attachment J

10/1/99 - 9/30/00

Page 1 of 1

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates	326				
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

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SIGNATURE OF C.E.C.

DATE SIGNED

11/3/00

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

22-R-0028

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY (Name and Address) (Include Zip Code) (Facility must be approved with USDA)

22-R-0028, Cust Id 168

BRISTOL-MYERS SQUIBB COMPANY
P.O. BOX 4000
PRINCETON, NJ 08543

APR 28 2000

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

Hopewell, NJ

Attachment I

10/1/99 - 9/30/00

Page 1 of 1

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

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4. Dogs			10		10
5. Cats					0
6. Guinea Pigs					0
7. Hamsters		105			105
8. Rabbits					0
9. Non-human Primates	87	40	40		167
10. Sheep					0
11. Pigs					0
12. Other Farm Animals					0
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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SIGNATURE OF

DATE SIGNED

11/3/00

APHIS FORM
(AUG 9)

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.

FORM APPROVED
OMB NO 0579-0038

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, include Zip Code) with USDA

22-R-0028, Cust Id 168

BRISTOL-MYERS SQUIBB COMPANY
P.O. BOX 4000
PRINCETON, NJ 08543

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, sheets if necessary.)

Use these purposes. Attach additional

FACILITY LOCATIONS (Sites)

Lawrenceville, New Jersey

Attachment K

10/01/99 - 03/31/00

Page 1 of 1

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. * TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	17	24	71		112
5. Cats					
6. Guinea Pigs	40	285	577		902
7. Hamsters		110	239		349
8. Rabbits		169	409		578
9. Non-human Primates	21		175		196
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIG

APR

DATE SIGNED

11/13/00

KAC

HEADQUARTERS

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

FORM APPROVED
OMB NO 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, include Zip Code) and with USDA

22-R-0028, Cust Id 168

BRISTOL-MYERS SQUIBB COMPANY
P.O. BOX 4000
PRINCETON, NJ 08543

NOV 28 2000

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, sheets if necessary)

for these purposes. Attach additional

FACILITY LOCATIONS (Sites)

Mount Vernon

Attachment G

4/1/00 - 9/30/00

Page 1 of 1

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C • D • E)
4. Dogs	48	11	57		68
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates	36	11	24		35
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

SIGNATURE OF

DATE SIGNED

11/3/00

APHIS FORM
(AUG 9'

ACC

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
22R0028

FORM APPROVED
OMB NO 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address - include Zip Code - with USDA)

22-R-0028, Cust Id 168

BRISTOL-MYERS SQUIBB COMPANY
P.O. BOX 4000
PRINCETON, NJ 08543

NOV 28 2000

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, sheets if necessary.)

For these purposes. Attach additional

FACILITY LOCATIONS (Sites)

Wallingford, CT

Attachment E

April 1, 2000 - September 30, 2000

Page 1 of 1

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs	8	9	24		33
5. Cats	0	0	0		0
6. Guinea Pigs	0	63	40		103
7. Hamsters	0	8	0		8
8. Rabbits	43	65	91		156
9. Non-human Primates	0	6	12		18
10. Sheep	0	0	0		0
11. Pigs	0	0	0		0
12. Other Farm Animals	0	0	0		0
13. Other Animals					
Woodchucks	0	0	1		1
Gerbils	36	3	110		113
Cotton Rats	41	18	154		172

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

SIGNATURE

DATE SIGNED

11/3/00

Kacc

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

DEC 1 2000

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.

FORM APPROVED
OMB NO 0579-0038

2. HEADQUARTERS include 22-R-0031, Cust Id 179

red with USDA

NEWARK BETH ISRAEL MEDICAL CENTER
201 LYONS AVENUE
NEWARK, NJ 07112

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

Only One Location

See Item #2

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	71	0	
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs	0	0	14	0	
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility
- 2) Each principal investigator has considered alternatives to painful procedures
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTES RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGNATURE

DATE SIGNED

11-28-00

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY
include Zip 22-R-0034, Cust Id 727

NEXTRAN COMPANY
303-B COLLEGE ROAD EAST
PRINCETON, NJ 08540

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

1) 901 CARPENTER ROAD
ALBANY, OH, 45710

2) 3400 22ND ST NW
ROCHESTER, MN, 55901

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs	436	245	650		895
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
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- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0037

CUSTOMER NUMBER: 752

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Rider University
2083 Lawrenceville Road
Lawrenceville, NJ 08648

Telephone: (609) -895-5435

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primate					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals <i>Spring mice</i>	300	200	25	0 (zero)	225

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGN

DATE SIGNED

12/6/00

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

22-R-0038

FORM APPROVED
OMB NO 0579-0036

2. HEADQUARTERS
include Zip

22-R-0038 Cust Id 677

(b)(6), (b)(7)(C)

BRACCO RESEARCH USA INC.
305 COLLEGE ROAD EAST
PRINCETON, NJ 08540

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

BRACCO RESEARCH USA INC.
305 College Road East
Princeton, NJ 08534

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					
		(Only rats & mice bred for research used)			

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

10/17/00

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

22-R-0041

FORM APPROVED
OMB NO 0579-0038

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS

Include ZL 22-R-0041, Cust Id 173

(with USDA)

BECTION DICKINSON AND CO.
ONE BECTION DRIVE
FRANKLIN LAKES, NJ 07417

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Listed)

Becton Dickinson Technologies
26 Davis Drive
RTP, NC 27709

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023AJ)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted (involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in those animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs	--	--	--	--	--
5. Cats	--	--	--	--	--
6. Guinea Pigs	--	860	--	--	860
7. Hamsters	--	--	--	--	--
8. Rabbits	--	306	24	--	330
9. Non-human Primates	--	--	--	--	--
10. Sheep	--	--	--	--	--
11. Pigs	--	--	55	--	55
12. Other Farm Animals	--	--	--	--	--
13. Other Animals	--	--	--	--	--

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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- The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTER'S RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (P. U.S.C. Section 2143).

DATE SIGNED

Sept. 25,
2000

PART - HEADQUARTERS

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

FORM APPROVED
OMB NO. 0579-0036

with USDA

2. HEADQUARTERS

include Zip 22-R-0043, Cust Id 991

(b)(6), (b)(7)(C)

CELSIS, INC.

NEW JERSEY DIVISION

165 FIELDCREST AVENUE

EDISON, NJ 08837

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

165 Fieldcrest Avenue
Edison NJ 08837

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs		0	0	0	0
5. Cats		0	0	0	0
6. Guinea Pigs		300	0	0	300
7. Hamsters		0	0	0	0
8. Rabbits		222	2	0	224
9. Non-human Primates		0	0	0	0
10. Sheep		0	0	0	0
11. Pigs		0	0	0	0
12. Other Farm Animals		0	0	0	0
13. Other Animals		0	0	0	0

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTES RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SI

DATE SIGNED

10/2/00

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

22-R-0064

FORM APPROVED
OMB NO 0679-0026

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA
include Zip Code)

Ortho-Clinical Diagnostics Inc.
Regulatory Affairs
1001 US Hwy 202
Raritan, NJ 08869-0606

OCT 15 2000

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

Ortho-Clinical Diagnostics, Inc. SITE 001
1001 US Hwy 202

Raritan, NJ 08869

Sterlingbrook Equine Trauma Center,
P.O. Box 609, Rt 513

Pittstown, NJ

SITE 002

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits	0	322	748	0	1070
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals	1	24	0	0	24
Goats					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility
- 2) Each principal investigator has considered alternatives to painful procedures
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF CEO OR INSTITUTIONAL OFFICIAL

DATE SIGNED

10/10/00

APHIS

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

22-R-0065

FORM APPROVED
OMB NO. 0579-0036

Registered with USDA

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS
Include Zip

22-R-0065, Cust Id 183

WILLIAM PATERSON UNIVERSITY OF NEW JERSEY
300 POMPTON ROAD
WAYNE, NJ 07470

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

Science Hall 206 & 208

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs					0
5. Cats					0
6. Guinea Pigs					0
7. Hamsters					0
8. Rabbits					0
9. Non-human Primates					0
10. Sheep					0
11. Pigs					0
12. Other Farm Animals					0
13. Other Animals					0
WE MAINTAINED ONLY LABORATORY MICE & RATS					
(b)(6), (b)(7)(C)					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGN

DATE SIGNED

8-28-98

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include): 22-R-0066, Cust Id 184

UNIVERSITY OF MEDICINE & DENTISTRY OF NJ
675 HOES LANE
PISCATAWAY, NJ 08854

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

See attached

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs			161		161
5. Cats					0
6. Guinea Pigs			2		2
7. Hamsters		88			88
8. Rabbits		6	262		268
9. Non-human Primates					0
10. Sheep			5		5
11. Pigs			28		28
12. Other Farm Animals					0
13. Other Animals					0

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 USC Section 2143)

SIGNATURE OF CEO OR INSTITUTIONAL OFFICIAL

NAME AND ADDRESS OF INSTITUTIONAL OFFICIAL

DATE SIGNED

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10/26/00

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

NOV 13 2000

2. HEADLINE

include 22-R-0076, Cust Id 189

Record with USDA

CAMDEN COUNTY COLLEGE
P.O. BOX 200
COLLEGE DRIVE
BLACKWOOD, NJ 08012

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	10	0	10	0	10
7. Hamsters	0	0	0	0	0
8. Rabbits	6	0	6	0	6
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					
chickens	0	12	0	0	12

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTES RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 USC Section 2143)

SIG

1)

DATE SIGNED

10/13/00

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS

include: 22-R-0094, Cust Id 187

and with USDA

BIOMATRIX, INC.
1125 PLEASANT VIEW TERRACE
RIDGEFIELD, NJ 07657

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	NA	NA	NA	NA	NA
5. Cats	NA	NA	NA	NA	NA
6. Guinea Pigs	NA	NA	NA	NA	NA
7. Hamsters	NA	NA	NA	NA	NA
8. Rabbits	NA	NA	29	NA	29
9. Non-human Primates	194	48	49	NA	97
10. Sheep	NA	NA	NA	NA	NA
11. Pigs	NA	NA	NA	NA	NA
12. Other Farm Animals	NA	NA	NA	NA	NA
13. Other Animals	NA	NA	NA	NA	NA

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTES RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGNATURE

DATE SIGNED

10/4/00

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

FORM APPROVED
OMB NO. 0579-0036

NOV 3 2000

2. HEADQUARTERS
include Zip Code 22-R-0099, Cust Id 194

with USDA

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

(b)(6), (b)(7)(C)
UNIVERSITY OF MEDICINE & DENTISTRY OF NJ
2 MEDICAL CENTER DRIVE
STRATFORD, NJ 08084

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

Vivarium First Floor
2 Medical Center Dr.
Stratford, NJ 08084

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs	2				2
7. Hamsters					
8. Rabbits	1				1
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTES RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SI

DATE SIGNED

10/26/00

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

22-R-0104

FORM APPROVED
OMB NO 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS

include Z 22-R-0104, Cust Id 198

CENTER FOR MOLECULAR MED & IMMUNOLOGY
520 BELLVILLE AVE
BELLEVILLE, NJ 07109

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters			330		330
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Mice		391	9687		10078
Rats			5		5

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTES RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF HEADQUARTES RESEARCH FACILITY OFFICIAL

DATE SIGNED

10-24-00

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0110
CUSTOMER NUMBER: 8209

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Morristown Memorial Hospital
Reeves Surgical Laboratories
100 Madison Avenue
Morristown, NJ 07962

Telephone: (973) -971-6256

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primate					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

INACTIVE

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGN

DATE SIGNED

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

FORM APPROVED
OMB NO 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS

include: 22-R-0116, Cust Id 695

ed with USDA

XENOBIOTIC LABORATORIES, INC.
107 MORGAN LANE
PLAINSBORO, NJ 08536

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

listed above.

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A.)

A Animals Covered By The Animal Welfare Regulations	B Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs	0	12	0	0	12
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use

CERTIFICATION BY HEADQUARTES RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 USC Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Print)

DATE SIGNED

10-06-00

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.

22-R-0117, Cust Id 701

FORM APPROVED
OMB NO 0579-0036

with USDA

2. HEADQUARTERS
include Zip Code

BARTON'S WEST END FARMS, INC.
161 JANES CHAPEL ROAD
OXFORD, NJ 07863

NOT A FOIA DELETION

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

Barton's West End Farms, Inc., 161 Janes

Alder Ridge Farms, Inc., 706 Township Road

Chapel Road, Oxford, NJ 07863

Lakewood, PA 18439-0290

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs		312	1		313
5. Cats					0
6. Guinea Pigs					0
7. Hamsters					0
8. Rabbits					0
9. Non-human Primates					0
10. Sheep					0
11. Pigs		12			12
12. Other Farm Animals					0
13. Other Animals					0

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGN

(initials)

DATE SIGNED

11-29-00

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

FORM APPROVED
OMB NO. 0579-0036

1 with USDA

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS
include Zip 22-R-0118, Cust Id 1672

PEDIATRIC CARDIOLOGY
137 PAVALION AVENUE
LONG BRANCH, NJ 07740

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

40 MORE Road.

TIMM FELD NJ 07740

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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CERTIFICATION BY HEADQUARTES RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE C

(ml)

DATE SIGNED

9/29/2000

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS

include Zip 22-R-0120, Cust Id 1701

* with USDA

QUALTECH LABORATORIES, INC.
104 GREEN GROVE ROAD
OCEAN, NJ 07712

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

As above

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A) *

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	19	0	19
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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CERTIFICATION BY HEADQUARTES RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

DATE SIGNED

11/28/00

NOV 28 2008

1. REGISTRATION NO.

FORM APPROVED
OMB NO. 0579-0038

in USDA

2. HEADQUARTERS
include Zip Code 22-R-0122, Cust Id 1804ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)EPIGENESIS PHARMACEUTICAL, INC.
P.O. BOX 7007
PRINCETON, NJ 08543

status: Active

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

2005 Eastpark Boulevard
Cranbury, NJ 08512

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates	11	15			15
10. Sheep	(Common Marmosets)				
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTER RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF CEO OR INSTITUTIONAL OFFICIAL

DATE SIGNED

11/17/2008

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

22R0123

FORM APPROVED
OMB NO. 0579-0036

2. HEADG include 22-R-0123, Cust Id 1824

red with USDA

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

COUNTY COLLEGE OF MORRIS
214 CENTER GROVE ROAD
RANDOLPH, NJ 07869

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

County College of Morris

Sheffield Hall, A-230

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	6	0	0	6
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

DATE SIGNED

11/28/14

can

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0125

FORM APPROVED
CMB NO. 0573-C036

CUSTOMER NUMBER: 11697

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)Hackensack University Medical Center
Institute For Biomedical Research
David Joseph Junat Research Bldg
30 Prospect Ave
Hackensack, NJ 07601

Telephone: (201)-996-2879

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for those purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A-1)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely effected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					0
5. Cats					0
6. Guinea Pigs					0
7. Hamsters					0
8. Rabbits					0
9. Non-human Primate					0
10. Sheep					0
11. Pigs					0
12. Other Farm Animals					0
13. Other Animals					0

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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- 4) The attending veterinarian for this research facility has adequate authority to ensure the utilization of adequate veterinary care to ensure the health and well-being of the animals and

DATE SIGNED

12/15/00

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0128

CUSTOMER NUMBER: 12247

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Collage Consulting
Po Box 29
340 Rt 46
Great Meadows, NJ 07838

Telephone: (908) -637-4687

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	0	0	0	0
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primate					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

DATE SIGNED

12/18/00

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

22-R-0009

FORM APPROVED
OMB NO. 0579-0038

2. HEADQUARTERS RESEARCH FACILITY
include Zip 22-R-0009, Cust Id 519

with USDA

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

(b)(6), (b)(7)(c)
NOVARTIS PHARMACEUTICALS CORPORATION
NOVARTIS PHARMACEUTICALS CORPORATION
BLDG 404, Rm. 460
EAST HANOVER, NJ 07936

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

East Hanover, NJ

Buildings 404&406

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purpose.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	60	421	10	38	469
5. Cats	N/A	N/A	N/A	N/A	N/A
6. Guinea Pigs	N/A	N/A	N/A	N/A	N/A
7. Hamsters	N/A	N/A	N/A	N/A	N/A
8. Rabbits	22	182	N/A	15	197
9. Non-human Primates	383	277	N/A	4	281
10. Sheep	N/A	N/A	N/A	N/A	N/A
11. Pigs	N/A	N/A	N/A	N/A	N/A
12. Other Farm Animals	N/A	N/A	N/A	N/A	N/A
13. Other Animals	N/A	N/A	N/A	N/A	N/A

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

11-29-00

FORM 18-23 (OCT 88), which is obsolete)

PART - HEADQUARTERS

USDA ANNUAL REPORT OF RESEARCH FACILITY FOR 1999-2000
NOVARTIS PHARMACEUTICALS CORPORATION
USDA Registration No. 22-R-0009

Summary of the NACUC approved exceptions to the Standards and Regulations:
 Canine Exercise Exemptions

	<u>Protocol Title</u>	<u>Species</u>	<u>Number</u>	<u>Days Without Exercise</u>	<u>Reason</u>
1.	Relative Absorbance of Formulations of Compound X	Dogs	02	6	Quantitative collection of excreta, containment of radioactivity
2.	Relative Absorbance of Formulations of Compound X	Dogs	06	9	Containment of radioactivity of excreta, containment of radioactivity
3.	N/A	Dogs	01	7	Surgical recovery of dogs neutered for permanent placement into adoptive homes
4.	N/A	Dogs	02	2	Lameness/sprain
5.	N/A	Dogs	01	8	Lameness/sprain
6.	N/A	Dogs	01	12	Lameness/sprain
7.	Relative Absorbance of Formulations of Compound X	Dogs	12	2	To prevent the dog from dislodging an indwelling IV catheter
8.	Relative Absorbance of Formulations of Compound X	Dogs	6	1	To prevent the dog from dislodging an indwelling IV catheter
9.	Training Techniques II	Dogs	8	20	Surgical recovery of dogs implanted with telemetry devices
10.	Training Techniques II	Dogs	2	19	Surgical recovery of dogs implanted with telemetry devices

OPTIONAL COLUMN E EXPLANATION FORM

4-WEEK CAPSULE TOXICOLOGY STUDY WITH A 2 WEEK-RECOVERY

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 32. Number of animals classified as category "E" - 1.
3. Species (common name) _____ Dogs _____ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

On day 29 of the study, this dog experienced disorientation, ataxia and an abnormal gait. The following day the dog recovered from these findings and was euthanized as scheduled.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)
6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

SAFETY PHARMACOLOGY STUDY

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 6. Number of animals classified as category "E" - 1.
3. Species (common name) _____ Dogs _____ of animals used in this study.
6. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

This dog exhibited a swollen limb with an interdigital cyst for three days during this study. This condition resolved and the dog was subsequently returned to our holding colony

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)
6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM
4-WEEK ORAL GAVAGE TOXICOLOGY STUDY

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 32. Number of animals classified as category "E" - 3.
3. Species (common name) _____ Dogs _____ of animals used in this study.
5. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

Three dogs demonstrated a non-weight bearing limb during this study, two each with a footsore. The conditions resolved and the dogs were euthanized as scheduled.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM
13-WEEK ORAL GAVAGE TOXICOLOGY STUDY

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 25. Number of animals classified as category "E" - 3.
3. Species (common name) _____ Dogs _____ of animals used in this study.
10. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

One dog each exhibited varying degrees of decreased locomotor activity and, in some cases, ataxia on days 66, 73 and 80 while on study. These dogs were euthanized on these respective days.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

As soon as there were signs indicating that these animals were experiencing pain or distress, they were euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

2-WEEK ORAL CAPSULE TOXICOLOGY STUDY

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 16. Number of animals classified as category "E" - 4.
3. Species (common name) _____ Dogs _____ of animals used in this study.
7. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

On day 17 of study these dogs experienced decreased locomotor activity, ataxia and impaired righting reflexes. The dogs showed recovery from these signs the following day and were euthanized as scheduled.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

MODIFIED ORAL GAVAGE 2WEEK RANGEFINDING STUDY

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 14. Number of animals classified as category "E" - 5.
3. Species (common name) _____ Dogs _____ of animals used in this study.
8. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

Four dogs experienced decreased locomotor activity and occasional muscle tremors 5 days prior to scheduled euthanasia. Two of the four dogs also exhibited moderate ataxia for three days. A fifth dog demonstrated a slight reduction in locomotor activity for three days. All were euthanized as per study schedule.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM
2-WEEK ORAL GAVAGE TOXICOLOGY STUDY

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 16. Number of animals classified as category "E" - 8.
3. Species (common name)_____Dogs_____ of animals used in this study.
9. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

One dog exhibited a hunched posture and lack of appetite which progressed into decreased locomotor activity the following day when it was euthanized.

Six dogs appeared to exhibit slightly decreased locomotor activity 2-4 days prior to their scheduled necropsy. Two of these dogs demonstrated slight ataxia and a moderate decrease of locomotor activity on the day they were euthanized.

The eighth dog presented with an interdigital cyst and was euthanized on day 5 of the study after also exhibiting a reduction of food consumption and emesis.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

4-WEEK ORAL CAPSULE TOXICOLOGY STUDY WITH A 2 WEEK RECOVERY

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 32. Number of animals classified as category "E" - 3.
3. Species (common name) _____ Dogs _____ of animals used in this study.
11. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

One dog on each of day 8 and day 15 of study exhibited dehydration, diarrhea and decreased locomotor activity and were euthanized. An additional dog was euthanized on day 15 after exhibiting dehydration and weight loss.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

As soon as there were signs indicating that these animals were experiencing pain or distress, they were euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

13-WEEK CAPSULE TOXICOLOGY STUDY WITH A 4 WEEK-RECOVERY

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 32. Number of animals classified as category "E" - 3.
3. Species (common name) _____ Dogs _____ of animals used in this study.
12. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

On day 16 of the study, one dog was found dead. The dog appeared normal except for diarrhea the day prior to this finding.

Two dogs experienced slight to severe decreased locomotor activity and ataxia on several days during dosing. These dogs recovered from these conditions following cessation of dosing.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

52 WEEK ORAL GAVAGE TOXICOLOGY STUDY WITH A 4 WEEK-RECOVERY

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 40. Number of animals classified as category "E" - 1.
3. Species (common name) _____ Dogs _____ of animals used in this study.
13. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

On day 302 of study this dog demonstrated decreased locomotor activity, diarrhea and was euthanized.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

As soon as there were signs indicating that this animal was experiencing pain or distress, it was euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

39 WEEK ORAL GAVAGE TOXICOLOGY STUDY WITH A 4 WEEK-RECOVERY

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 32. Number of animals classified as category "E" - 3.
3. Species (common name) _____ Dogs _____ of animals used in this study.
14. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

An accidental misdose occurred to three dogs on this study. The dogs exhibited respiratory difficulty and were euthanized the same day. Alternatives in dosing techniques were reviewed and a decision was made to limit the dosing of animals to those who were the most experienced in oral gavage.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

As soon as there were signs indicating that these animals were experiencing pain or distress, they were euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)

OPTIONAL COLUMN E EXPLANATION FORM

TWO WEEK ORAL GAVAGE BID STUDY

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 10. Number of animals classified as category "E" - 1.
3. Species (common name)____Non-human Primates-Crab eating Macacque____ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These animals were dosed with a pharmaceutical compound.

One monkey was euthanized due to decreased food consumption, pale appearance and thin condition.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

As soon as there were signs indicating that this animal was experiencing pain or distress, it was euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).

OPTIONAL COLUMN E EXPLANATION FORM
SINGLE DOSE MARMOSET IV TOXICOLOGY STUDY

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 4. Number of animals classified as category "E" - 1.

3. Species (common name)____Non-human Primates-Common Marmoset____ of animals used in this study.

4. Explain the procedure producing pain and/or distress.

These animals were dosed with a pharmaceutical compound.

One marmoset exhibited moderate to severely decreased locomotor activity, ataxia and impaired righting reflex and was euthanized on day 10 of study.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

As soon as there were signs indicating that this animal was experiencing pain or distress, it was euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).

OPTIONAL COLUMN E EXPLANATION FORM

3 CYCLE MARMOSSET

1. Registration Number: 22-R-0009

2. Number of animals used in this study – 8. Number of animals classified as category "E" - 2.

3. Species (common name)____Non-human Primates-Common Marmoset____ of animals used in this study.

4. Explain the procedure producing pain and/or distress.

These animals were dose with a pharmaceutical compound.

Two marmosets were euthanized on day 7 and day 13 respectively after exhibiting soft feces and/or diarrhea for several days prior to euthanasia and clinical signs associated with moribidity on the day they were euthanized.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

As soon as there were signs indicating that these animals were experiencing pain or distress, they were euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).

OPTIONAL COLUMN E EXPLANATION FORM

AN ORAL EMBRYO-FETAL DEVELOPMENT STUDY IN RABBITS

1. Registration Number: 22-R-0009
2. Number of animals used in this study –100. Number of animals classified as category "E" - 2.
3. Species (common name)____Rabbits____ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These animals were dosed with a pharmaceutical compound.

One rabbit was found dead after displaying labored respiration and convulsions. A second rabbit was euthanized after displaying decreased locomotor activity and convulsions.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

As soon as there were signs indicating that these animals were experiencing pain or distress, they were scheduled to be euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).
- 2) Guideline on detection of toxicity to reproduction for medicinal products published in the Federal Register on September 22, 1994 (FR 48746).

OPTIONAL COLUMN E EXPLANATION FORM

AN EXPLORATORY STUDY TO EVALUATE TOLERABILITY IN RABBITS

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 42. Number of animals classified as category "E" - 9.
3. Species (common name) _____ Rabbits _____ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These animals were dosed with a pharmaceutical compound.

Eight rabbits were euthanized the day they exhibited labored respiration, five of which exhibited decreased locomotor activity. One rabbit was euthanized on the same day of study after it exhibited a red nasal discharge.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

As soon as there were signs indicating that these animals were experiencing pain or distress, they were euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).
- 2) Guideline on detection of toxicity to reproduction for medicinal products published in the Federal Register on September 22, 1994 (FR 48746).

OPTIONAL COLUMN E EXPLANATION FORM

AN ORAL EMBRYO-FETAL DOSE RANGE FINDING STUDY IN RABBITS

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 30. Number of animals classified as category "E" - 4.
3. Species (common name)____Rabbits____ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These animals were dosed with a pharmaceutical compound.

Four rabbits were found dead on this study. These animals exhibited labored respiration the day prior to being found dead. The other animals in these dose groups were electively euthanized prior to any clinical signs being exhibited.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922).
- 2) Guideline on detection of toxicity to reproduction for medicinal products published in the Federal Register on September 22, 1994 (FR 48746).

OPTIONAL COLUMN E EXPLANATION FORM

ABSOLUTE BIOAVAILABILITY OF A PHARMACEUTICAL COMPOUND IN THE DOG

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 3. Number of animals classified as category "E" - 3.
3. Species (common name)____Dogs____ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These animals were dosed with a pharmaceutical compound as part of a bioavailability study. The findings in these dogs were completely unexpected. The first dog died on the first day of the study. The other two dogs were treated by the veterinary staff with supportive therapy for the clinical signs which they exhibited. These animals were euthanized on day 3 after the study.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

As soon as the unexpected signs were seen in these dogs, the veterinary staff began monitoring these dogs and treating their clinical signs.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
22-R-0025

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

Rutgers-State University of NJ
Research & Sponsored Programs
58 Bevier Road
Piscataway, New Jersey 08854-8010

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

See Attached

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	2	13		11	24
5. Cats		2			2
6. Guinea Pigs			219		219
7. Hamsters		138			138
8. Rabbits	6	6	174		180
9. Non-human Primates		3	4		7
10. Sheep					
11. Spiny Mouse		42			42
12. Other Farm Animals					
Hedge hog		1			1
13. Other Animals					
Gerbil	10	304			304
Ferret		46			46
Deer		5			5

ASSURANCE STATEMENTS

1. Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
2. Each principal investigator has considered alternatives to painful procedures.
3. This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
4. The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

11-30-00

NOT A FOIA DELETION

The principal investigator for animal proposal [REDACTED] needs to provide written justification for not relieving more than momentary or slight pain or distress to the animals.

Investigators Response:

NOT A FOIA DELETION

The objective of this study was determine [REDACTED] (an experimental chemotherapeutic agent) single dose acute toxicity and observed its dose-limiting toxicities. The FDA requires that test compounds be administered to animals to identify doses causing no adverse effect and doses causing major (life threatening) toxicity (CDER, 1996). Acute toxicity studies in animals are necessary for any pharmaceutical intended for human use. Important information gathered from these studies include mortalities, clinical signs, time of onset, duration and reversibility of toxicity (61 FR 43934). The information obtained from these studies is useful in choosing doses for repeat-dose studies, providing preliminary identification of target organs of toxicity, and, occasionally, revealing delayed toxicity. Acute toxicity studies also aid in the selection of starting doses for Phase I human trials.

Experimental endpoints for euthanasia were established in this protocol to minimize pain and discomfort in animals. These endpoints included both hematological (severe drops in hematocrit, leukocytes and platelets) and gross clinical observations (>20% weight loss, lethargy, continued vomiting and/or diarrhea). However, this study did not prescribe sedatives and/or analgesics at the onset of adverse clinical observations. Sedatives and analgesics would potentially interfere with the test article's normal pharmacokinetics and pharmacodynamics. In addition, the use of these agents would not allow the investigator to observe the normal duration or reversibility of potential toxicity. Therefore, these agents were not used because their induced aberrations would undermine the studies objectives and reduce the data's value to the FDA.

Site: 1 Busch Campus
Piscataway, NJ 08854
(b)(6), (b)(7)c Psychology, Gordon Rd., ARC)
County: Middlesex

Contact Person:
(b)(6), (b)(7)c

Site: 2 Cook Campus
New Brunswick, NJ 08901
(Bartlett Hall, PSARF Complex)
County: Middlesex

Contact Person:
(b)(6), (b)(7)c

Site: 3 Newark Campus
197 University Avenue
Newark, NJ 07102
(b)(6), (b)(7)c
County: Essex

Contact Person:
(b)(6), (b)(7)c

Site: 4 Camden Campus
Camden, NJ 08101
(Science Bldg.)
County: Camden

Contact Person:
(b)(6), (b)(7)c

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

FORM APPROVED
OMB NO. 0579-0036ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA,
include Zip 22-R-0032, Cust Id 180HOFFMANN-LAROCHE, INC.
RESEARCH & DEVELOPMENT DIV.
340 KINGSLAND STREET
NUTLEY, NJ 07110

NOV 1 1990

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, attach additional sheets if necessary.)

Attach additional

FACILITY LOCATIONS (Sites)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	116	278	0	2	280
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	320	0	0	320
7. Hamsters	0	0	0	0	0
8. Rabbits	13	228	0	26	254
9. Non-human Primates	11	24	28	0	52
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals involved.
- The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of animal care and use.

(b)(6), (b)(7)(c)

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
		11/9/00

APHIS FORM 7023
(AUG 91)

(Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 1 - HEADQUARTERS

Optional Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 22-R-0032
2. Number 2 of animals used in this study.
3. Species (common name) Dog of animals used in this study.
4. Explain the procedure producing pain and/or distress.

See attached

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency FDA CFR 21 CFR 58.3(d)
21 CFR 58.90

Hoffmann-La Roche
22-R-0032

USDA Category E description:

Dog:

A total of 2 dogs from a group of animals used in studies to evaluate drug candidates for clinical trials were identified as Category E. One dog was in a study to evaluate an anti-asthmatic compound and was found dead without prior clinical signs. One dog was in the high dose group for a study to evaluate a compound for the treatment of emphysema and showed clinical signs of toxicity. Both studies were designed and conducted in accord with guidelines established by the FDA. Veterinary personnel observed all animals on study on a daily basis and provided supportive care when needed.

Optional Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 22-R-0032
2. Number 26 of animals used in this study.
3. Species (common name) Rabbit of animals used in this study.
4. Explain the procedure producing pain and/or distress.

See Attached

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency FDA CFR 21 CFR 58.3 (d)
21 CFR 58.90

USDA Category E description:

Rabbit:

A total of 26 rabbits from a group of animals used in studies to evaluate the teratogenicity of drug candidates for clinical trials were identified as Category E. These animals were from several different groups used to evaluate compounds in the following studies:

1. Three pregnant rabbits in a group used to evaluate a glucose-lowering agent for the treatment of diabetes aborted after drug administration.
2. In a study to evaluate a compound for the treatment of emphysema, 11 rabbits died and 1 aborted following administration of the drug.
3. In a study to evaluate a chemotherapeutic compound, 4 rabbits showed clinical signs of inappetence, lethargy and weight loss. A total of 2 rabbits died while on study.
4. In a study to evaluate an anti-asthmatic compound, 5 rabbits aborted after drug administration.

These studies were designed and conducted in accord with guidelines established by the FDA. Veterinary personnel observed all study animals daily and provided supportive care when needed.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
22-R-0036

FORM APPROVED
OMB NO 0579-0036

2. HEAT
inclu 22-R-0036, Cust Id 181

stored with ASDA

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

SCHERING CORPORATION
2015 GALLOPING HILL ROAD
KENILWORTH, NJ 07033

DEC 6 2000

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

Schering-Plough Research Institute

1. 2015 Galloping Hill Road, Kenilworth, NJ 07033

Schering-Plough Research Institute, Safety Evaluation Center,

2. PO Box 32 Lafayette, NJ 07848

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	10	227	271	4	502
5. Cats	0	0	29	0	29
6. Guinea Pigs	0	6353	6607	0	12,960
7. Hamsters	0	0	0	0	0
8. Rabbits	0	885	199	4	1,088
9. Non-human Primates	104	436	295	12	743
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					
Gerbils	0	240	4140	0	4,380

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTES RESEARCH FACILITY OFFICIAL.
(Chief Executive Officer or Legally Responsible Institutional Official)
I certify that the above is true, correct, and complete (7 USC Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
		11/28/00

KAC

November 27, 2000

Elizabeth Goldentyer, DVM
UNITED STATES DEPARTMENT OF AGRICULTURE
Animal and Plant Health Inspection Service
Regulatory Enforcement and Animal Care
Eastern Region Office
920 Main Campus Drive
Unit 3040
Raleigh, NC 24606

Dear Dr. Goldentyer:

Listed below are comments to accompany the annual report of research facilities for site number 1.

One exception to the canine exercise program is to be reported. It involved the use of special canine metabolism cages for drug metabolism studies. The canine metabolism cages provide greater than 100%, but less than 200% of required space for exercise. The period of time is usually less than 10 days. Positive human interaction is greatly increased during this period. The protocols with the exemption are approved by the IACUC and reviewed during the semi-annual program review. The studies are infrequent and involved only sixteen laboratory canines.

The environmental enrichment program has exceptions for social housing for nonhuman primates. Eighteen squirrel monkeys and twenty-five rhesus monkeys are housed separately for special study needs for controlling and monitoring food consumption as part of the research projects. Fifty-two cynomolgus monkeys were housed separately for brief periods for drug metabolism studies or telemetric monitoring. All the animals are included in all the other aspects of the environmental enrichment program. The protocols with the exemption are approved by the IACUC and reviewed during the semi-annual program review.

Listed below are comments to accompany the annual report of research facilities for site number 2.

The dogs, rabbits and nonhuman primates listed in column "E" were used in standard toxicological investigations for new drug development. Because one purpose of toxicological studies was to define the pharmacokinetic and metabolic profiles of new chemical entities, potential drug interactions were not known during the course of the studies. Administration of anesthetics, tranquilizers, and/or analgesics could result in additive toxicities which would be detrimental to the animal's well-being. In addition, close monitoring was critical to determine whether or not the compounds had any detrimental effects. These agents were, therefore, withheld in accordance with protocols which were carefully reviewed and approved by the IACUC.

All animals were carefully monitored and if found to be in pain and/or distress during the course of the study were provided humane euthanasia. Animals, in which adverse clinical findings were identified but were not determined by the Staff Veterinarian to be of a serious nature, were allowed to continue to the completion of the study, but were also reported in column "E" of this annual USDA report. The studies were conducted in accordance with FDA requirements [21CFR 312.23(a)(8), 21 CFR 58, 62 FR 62922, and 59 FR 48746].

USDA Fiscal Year 2000 Exemptions from Site 2 For Animal Care and Use

Listed below are instances wherein animals were exempted from the pair-housing requirement of our program for the psychological well-being of non-human primates. The duration of such exemptions varied according to the reason. The numbers of animals and reasons for such exemptions are herein listed:

1. All non-human primates were exempted from social housing for periods of time when required for collection of individual clinical signs and required randomization of the animals in studies or during the quarantine period. The exemption from social housing was variable and ranged from 2 weeks to 6 months, depending on the duration of the individual study. All study protocols were reviewed and approved by the IACUC.
2. Eight non-human primates were exempted from social housing due to a transient medical condition as specified by the Staff Veterinarian, the duration of the exemption varied depending upon the medical condition.
3. Seven non-human primates were exempted from social housing due to being the documented aggressor in a pair-housing situation on at least two occasions.

There were 296 dogs exempted from our exercise program for dogs during the dosing period of studies where necessary to avoid coprophagia and observe for emesis. All protocols including this exemption were reviewed and approved by the IACUC.

This report is required by law (7 USC 2143). Failure to report according to the regulations can

See attached form for additional information

Emergency Report Control N

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

NOV 28 2000

1. CERTIFICATE NUMBER: 22-R-0069
CUSTOMER NUMBER: 185

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Consumer Product Testing Co., Inc.
70 New Dutch Lane
Fairfield, NJ 07004

Telephone: (201) 808-7111
973

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS (COLUMN: C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs	61	2484	0	52	
7. Hamsters	0	12	0	0	2536
8. Rabbits	18	1077	0	0	12
9. Non-human Primate				184	1261
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGN

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

11/28/00

APHIS Form 7023A
(AUG 91)

(Replaces VS FORM 18-23 (OCT 88), which is obsolete)

Annual Report - Site Listing:**Customer ID and Site Address:**

ID: 185

70 New Dutch Lane
Fairfield, NJ 07004
County: Essex

Telephone



EST. 1975

Consumer Product Testing Co.

Facility Registration Number: 22-R-0069

The animals listed in Column E of APHIS Form 7023 included 52 guinea pigs and 184 rabbits. The rabbits were used on irritation studies. These studies are used to determine the dermal, ocular or oral mucosa irritation potential of the articles tested. The guinea pigs were used on sensitization studies. These studies were used to determine the sensitization potential of the products tested.

In all cases the "procedures producing pain or distress" were either the injection of an adjuvant or the application of an irritating substance to the animal(s) in question. The sponsors of these studies had indicated that the use of anesthetics or analgesics might have interfered with the interpretation of the test results.

As a contract facility, we are not always aware of the nature of the articles being tested and rely upon our sponsors to responsibly determine the appropriateness of use of anesthetics and/or analgesics.

At the USDA's suggestion, we have included in Column E animals exhibiting maximum irritation scores in the above mentioned study types but not necessarily having exhibited behavioral responses normally associated with pain or distress. In cases where an animal had exhibited a behavioral response normally associated with pain or distress, the response was no more than momentary but the procedure was recorded as "painful" nonetheless.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0082
CUSTOMER NUMBER: 190

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Product Safety Labs., Inc.
725 Cranbury Road
East Brunswick, NJ 08816

Telephone: (908) -254-9200

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0				
5. Cats	0				
6. Guinea Pigs	0	1246	0	204	5150
7. Hamsters	0	8	0	0	8
8. Rabbits	0	1829	51	84	1964
9. Non-human Primate	0				
10. Sheep	0				
11. Pigs	0				
12. Other Farm Animals	0				
13. Other Animals					
Gerbils	0	180	0	0	180

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
		12/12/00

ATTACHMENT TO USDA/APHIS ANNUAL REPORT OF RESEARCH FACILITY

EXPLANATION OF COLUMN "E" ENTRIES

62 Rabbits – Eye Irritation Test (OPPTS 870.2400): Nine (9) of these animals vocalized following instillation of the test compound but immediately became calm after they were returned to their cage. Therefore, anesthetic was not considered. Although the remaining animals did not exhibit overt signs of pain or distress, they exhibited ocular irritation scores above an arbitrary threshold and were considered to be in pain as a result of their exposure to the test compound. Although in the eye irritation test ocular anesthetic may be used prior to instillation, repeated and/or prolonged anesthetic use could retard healing and possibly lead to collateral irritation and/or subsequent corneal infection. Therefore, ocular anesthetic was not used on the animals evidencing ocular irritation scores above this established threshold limit.

22 Rabbits – Dermal Irritation Test (OPPTS 870.2500): All animals exhibited eschar and/or corrosion at the dose site, which could indicate possible necrosis of the skin. In all cases, the area of exposure and subsequent skin damage was ≤ 1 in². Continuous or prolonged use of topical or systemic anesthetic agents during dermal irritation tests was not considered appropriate since it could lead to study complications including increased irritation and delayed healing. The use of analgesic agents would be inappropriate in these studies due to resultant anti-inflammatory effects that could mask the indicators of irritation. If used, they might significantly alter the effects of the test compound and compromise study results.

204 Guinea Pigs – Dermal Sensitization Test (OPPTS 870.2600): Similar to the dermal irritation test noted above, these animals exhibited eschar and/or corrosion at the dose site, which could indicate possible necrosis of the skin. In all cases, the area of exposure and subsequent skin damage was ≤ 1 in². Continuous or prolonged use of topical or systemic anesthetic agents during dermal sensitization tests was not considered appropriate since it could lead to study complications including increased irritation and delayed healing. The use of analgesic agents would be inappropriate in these studies due to resultant anti-inflammatory effects that could mask the indicators of sensitization. If used, they might significantly alter the effects of the test compound and compromise study results.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 22-R-0088

FORM APPROVED
OMB NO. 0579-0038

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)
FMC Corporation
Corporate Toxicology
P.O. Box 8
Princeton, NJ 08543
Status: Active

REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

See Attached

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
Dogs					
Cats					
Guinea Pigs		109			109
Hamsters					
Rabbits		174		70	181
Non-human Primates					
Sheep					
Pigs					
Other Farm Animals					
Other Animals					

SURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 USC Section 2143).

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

APHIS FORM 7023
(AUG 91)

(Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 1 - HEADQUARTERS

FMC Toxicology Laboratory
USDA Annual Report

RE: Registration No. 22-R-0088

The 7 rabbits listed in Category "E" were used in Primary Eye Irritation studies and where the use of anesthetics, analgesics, or tranquilizing agents are not allowed by regulatory guidelines (**United States EPA Health Effect Test Guidelines: OPPTS 870.2400**). The use of these pain-relieving agents could potentially interfere with the results of these studies. While these studies have the potential to produce more than minimal pain or distress to the animals by causing irritation, this study design is required by the regulatory agencies to determine positive responses to test compounds. **Currently there are no known or accepted alternatives to this testing procedure.**

It is currently and will continue to be FMC's policy, "Animals showing severe and enduring signs of pain or distress, will be humanely euthanized".

The Rabbit Primary Eye Irritation study design is as follows: The rabbit eyes are pre-tested the day prior to dosing to ensure they are acceptable for use. On the day of dosing, a small amount of the test compound is then administered by placing it in the bottom lid of the left eye and gently held closed for approximately one second. The eye is then scored using the Draize scoring method at 24, 48, 72 hours and again on study day 7.

138-139

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No
0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

22-R-0108

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include:

22-R-0108, Cust Id 193

EXXONMOBIL BIOMEDICAL SCIENCES, INC.

P.O. BOX 971

1545 ROUTE 22 EAST

ANNANDALE, NJ 08801

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, training, or experimentation, or more for those purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

Same as #2

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	--	--	--	--	--
5. Cats	--	--	--	--	--
6. Guinea Pigs	75	249	--	31	280
7. Hamsters	--	--	--	--	--
8. Rabbits	--	59	--	4	63
9. Non-human Primates	--	--	--	--	--
10. Sheep	--	--	--	--	--
11. Pigs	--	--	--	--	--
12. Other Farm Animals	--	--	--	--	--
13. Other Animals	--	--	--	--	--

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL (Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 USC Section 2143).

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

11/28/00

Attachment to Exxon Biomedical Sciences Inc. Annual Report of Research

Three study types were identified as potentially producing pain or distress in rabbits or guinea pigs at ExxonMobil Biomedical Sciences, Inc. (EMBSI) during the 1999 - 2000 APHIS census year. All three study types followed accepted regulatory or international test guidelines (OECD 404, 405 and 406) and were conducted for regulatory purposes. These study types and the related procedures are listed below:

Ocular Irritation Studies: Involved the administration of 0.1 ml or 0.1 grams of test substance into conjunctival sac of the rabbit eye. The rabbits were then observed daily until termination.

Dermal Irritation Studies: Involved the administration of 0.5 ml or 0.5 grams of test substance onto a 1" x 1" area of skin. The skin is exposed to the test substance for four hours under a semi-occluded dressing. The rabbits were then observed daily until termination.

Guinea Pig Sensitization Studies: Involved an intradermal injection of the test material in Freund's complete adjuvant to the clipped scapular area followed by a topical administration of the test material over the injection sites in an attempt to induce sensitization. All animals were topically challenged on a naive clipped site after a two-week rest period following the induction phase. The animals were observed daily and evaluated for dermal irritation 24 and 48 hours after all applications of the test substance.

Because the measure of pain in animals can not always be determined with certainty, the criteria listed in Appendix A were used for determining pain or distress for rabbits or guinea pigs used for the above study types conducted at EMBSI. These criteria, revised in 1997, are consistent with the definition of "painful procedures" defined in 9CFR, Subchapter A, Animal Welfare, Part 1 as well as scientific literature on the subject. The revised criteria developed in 1997 were in response to specific comments made by USDA during a January 1997 inspection, and upon the review of our IACUC.

Between October 1, 1999 and September 30, 2000, 21 animals were considered to exhibit some degree of pain or distress based on the criteria listed above. The following is a list of the number of animals considered possibly to be in pain or distress and the reason for the pain or distress.

# of Animals	Reason for possible pain or distress
3 Rabbits	Conjunctival redness score of "3", chemosis score greater than "2", and corneal dye retention indicative of ulceration - Ocular Irritation Studies
1 Rabbit	Irritation score of "4" - Dermal Irritation Studies
17 Guinea Pigs	Irritation score of "3" - Guinea Pig Sensitization Studies
14 Guinea Pigs	Emaciated - Guinea Pig Sensitization Studies

None of the animals listed above were treated for pain or distress. However, the guinea pigs that were emaciated were given water dishes and moistened food.

Attachment to Exxon Biomedical Sciences Inc. Annual Report of Research (cont'd)

The animals were not treated for pain or distress because the effects of anesthetic agents on the study outcome were not known. In ocular irritation tests and dermal irritation tests, recovery is a key endpoint of the study. Anesthetic agents may affect this recovery process. In guinea pig sensitization tests, the animals must be observed for a designated period of time and in some instances be rechallenged to generate meaningful data. Also, in the ocular irritation and dermal irritation studies where the animals received only a single exposure, any pain or distress that may have occurred did not persist or progress, *i.e.*, the responses observed in the studies were transient. The Study Directors for each of these study types were aware of the effects seen in the animals and monitored the animals' health.

Summary of 1999 - 2000 USDA Animal Usage

Species	# Animals used	# Animals with pain
Rabbits	63	4
Guinea Pigs	280	31

References:

Mroczek, N. S. Recognizing Animal Suffering and Pain. *Lab Animal* Volume 21, Number 9: 27-31, 1992

OECD, Organization for Economic Cooperation and Development, Guidelines for the Testing of Chemicals, Test Guideline 405, 1987.

OECD, Organization for Economic Cooperation and Development, Guidelines for the Testing of Chemicals, Test Guideline 406, 1992.

Report of the Laboratory Animal Science Association Working Party. The assessment and control of the severity of scientific procedures on laboratory animals. *Laboratory Animals* 24: 97-130

Appendix A

Signs of Pain and Distress Clinical Signs

The following are considered clear signs of animals in pain or distress.

Convulsions	Coarse Tremors	Dyspnea
Respiratory Arrhythmia	Hyperpnea	Hypopnea
Wet rales	Emaciation	Hypothermia
Abdominal Gripping	Prolapsed uterus	Prolapsed rectum
Teeth Grinding	Dystocia	Ranting (other than momentary)
Foot stomping (other than momentary)		

Additionally, any animal that can not access its food or water will be considered an animal in pain or distress.

Dermal Irritation

Erythema score of "4" (Draize scale)	Edema score greater than "2" (Draize scale)
Dermal irritation score of "3" (Buehler scale)	Eschar
Dermal sore/ulceration	Necrosis
Fissuring	Blanching (full depth)

Ocular Irritation

Conjunctival redness score of "3"	Conjunctival chemosis score greater than "2"
Conjunctival necrosis	Conjunctival ulceration
Iris score of "2"	Corneal opacity score greater than "2"
Blistering conjunctiva	Ruptured eye
Protruding cornea	Pannus
Corneal dye retention indicative of ulceration	

The following are considered subjective signs of animals in pain or distress. The observation of any one of these signs would not be considered sufficient to consider an animal in pain or distress. However, the occurrence of these signs with other related clinical signs may be considered a sign of pain or distress. The Study Director will make the determination of whether an animal with these signs was in pain or distress.

Ataxia	Fine Tremors	Piloerection
Aggressive	Ranting	Foot stomping
Teeth chattering	Vocalizing	Abdominal Staining
Cyanosis	Unthrifty coat	Small amount of stool
No stool	Distended abdomen	Food consumption Decrease
Red ocular discharge		

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 22-R-0124
CUSTOMER NUMBER: 1828

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Aventis
Route 202-206 Bldg M Room 243-B
Po Box 6800
Bridgewater, NJ 08807

Telephone: (908) -231-3317

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	50			50	50
5. Cats					
6. Guinea Pigs	341		6377	50	6427
7. Hamsters					
8. Rabbits				14	14
9. Non-human Primate	8				
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and

BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Officer or Legally Responsible Institutional Official)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED



November 28, 2000

USDA Annual Report

Registration #: 22-R-0124

Explanation of Category 'E' Animals

04-99-037: (Primary Eye Irritation Studies in Rabbits)

These studies assess the ocular irritation potential of new compounds, to support registration requirements, set workplace exposure limits, and provide data for health hazard information. Some discomfort due to the irritating effects of the test material may be unavoidable. Analgesics, anesthetics, or tranquilizing drugs can not be used. The possible interactions with the novel compounds being tested introduce unacceptable variables, possibly mask the treatment effects clinically and histologically, confound or prevent conclusions about toxicity, and may invalidate the studies, making them unacceptable for submission.

of Category E animals: 6 rabbits

06-99-048: (Dog Toxicity Studies)

This study establishes dosage ranges for novel compounds by characterizing a variety of toxicokinetic parameters as required by the FDA for IND submissions. Some sensation experienced due to pharmacotoxic effects and some discomfort due to the toxic effects at the higher doses of the test material will be unavoidable in some studies. Analgesic, anesthetic, or tranquilizing drugs cannot be used. The possible interactions with novel compounds being tested introduce unacceptable variables which would invalidate the study.

of Category E animals: 50 dogs

03-00-216: (Guinea Pig Sensitization Study)

This test evaluates substances for potential dermal sensitization and complies with the standards set forth in the Toxic Substances Control Act and other regulatory test rules. It is used as a predictive test for the safety assessment of novel compounds. Analgesics, anesthetics, or tranquilizing drugs cannot be used. The possible interactions with the novel compounds being tested would introduce unacceptable variables, possibly mask the treatment effects, confound or prevent conclusions about toxicity, and invalidate the studies, making them unacceptable for submission.

of Category E animals: 50 guinea pigs

02-99-014: (Primary Dermal Irritation Studies)

Primary skin irritation studies provide information to the humans who will be handling these compounds in the manufacturing process. Data from these studies are used to provide health hazard information for Material Safety Data Sheets (MSDS) and labels. Analgesic, anesthetic, or tranquilizing drugs cannot be used. The possible interactions with the novel compounds being tested would introduce unacceptable variables, possibly mask the treatment effects clinically, and histologically, confound or prevent conclusions about toxicity, and may invalidate the studies, making them unacceptable for submission.

of Category E animals: 8 rabbits

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

22-R-0126

FORM APPROVED
OMB NO 0579-0038

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT) **NOV 28 2000**

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

BASF Corporation
Quakerbridge road
P.O. Box 400
Princeton, NJ 08543-0400

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

LOCATIONS (Sites)

Quakerbridge and Clarksville Roads
Princeton, NJ 08543

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs		72		19	91
7. Hamsters					
8. Rabbits		46		18	64
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

Testify that the above is true, correct, and complete (7 USC Section 2143)

E.O.

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

[Signature]

Explanation of Column E Entry

The 18 rabbits listed in Column E were used for ocular irritation studies or dermal irritation studies. These studies were performed using the Guidelines published in the Federal Register, EPA Health Effects Guidelines, OPPTS 870.2400 (ocular irritation) and OPPTS 870.2500 (dermal irritation). The data provided by these studies is used to evaluate the toxic and irritant potential of novel proprietary compounds. This information is an integral part of the product submission packets provided to federal and foreign governmental agencies.

The concurrent administration of other chemicals, including analgesic and anesthetic compounds, to the test animals has the potential to mask or alter adverse signs. In addition, the administration of other chemicals might interact with the test articles. Either effect would interfere with the proper evaluation of the test results.

The criteria used to determine column E entry is based on the Draize¹ scoring system. Any animal in a primary eye irritation study that has a score of 2 or more for either corneal opacity or conjunctival irritation (redness or swelling, discharge is excluded) and/or an iris score of 1 at anytime during the course of the study or any animal in a primary dermal irritation study that has a score of 2 for either erythema or edema at anytime during the course of the study are placed in column E.

These studies were reviewed and approved by the Institutional Animal Care and Use Committee.

¹ Draize, H.J., Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics, Assoc. of Food and Drug Officials of the United States, 3rd Printing, 1975, page 51.

Explanation of Column E Entry

The 19 guinea pigs listed in Column E were used for dermal sensitization studies. These studies were performed using the Guidelines published in the Federal Register, EPA Health Effects Guidelines, OPPTS 870.2600. The data provided by these studies is used to evaluate the irritant potential of novel proprietary compounds. This information is an integral part of the product submission packets provided to federal and foreign governmental agencies.

The concurrent administration of other chemicals, including analgesic and anesthetic compounds, to the test animals has the potential to mask or alter adverse signs. In addition, the administration of other chemicals might interact with the test articles. Either effect would interfere with the proper evaluation of the test results.

The criteria used to determine column E entry is based on the Buehler¹ scoring system. Any animal in a skin sensitization study that has a score of 2 for erythema at anytime during the course of the study are placed in column E.

These studies were reviewed and approved by the Institutional Animal Care and Use Committee.

¹ Buehler, E. V., Fd. Chem. Toxic, Vol. 32, No.2, pp. 97-101, 1994

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

22-R-0127

FORM APPROVED
OMB NO 0579-0036

NOV 15 2000

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

Fort Dodge Animal Health
P.O. Box 5366
Quakerbridge Road
Princeton, NJ 08543-5366

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

Quakerbridge and Clarksville Roads
Princeton, NJ 08543

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits		7		1	8
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Gerbils		768		2	770

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
		11/7/00

USDA Annual Report – 2000
Fort Dodge Animal Health
Registration Number 22-R-0127

NOV 15 2000

The 2 gerbils reported in Category E were used in efficacy testing of novel compounds for *in vivo* anthelmintic activity. The compounds were administered in the feed or as a single oral dose. Premonitory signs were not observed during the day the animals were put on test. These gerbils were found dead during the routine morbidity and mortality check performed the next morning. This finding was not anticipated. Because the interval between onset of signs, if any, and death could not be determined, an assumption has been made that these gerbils could have experienced more than transient pain or distress prior to death.

This protocol was reviewed and approved by the Institutional Animal Care and Use Committee.

NOV 15 2000

The rabbit listed in Column E was part of a group of rabbits used to evaluate potential new acaricides. The animals on this protocol have a low level of *Psoroptes cuniculi* infestation and are closely monitored to prevent an over infestation. The morning following a routine ear cleaning, this rabbit was observed to have mild swelling of the base of the ears. This reaction was unexpected. Because the interval between onset of these signs and observation can not be established, an assumption has been made that this rabbit experienced more than momentary discomfort before intervention occurred.

This protocol was reviewed and approved by the Institutional Animal Care and Use Committee.

164-165

2. HEADQUARTER
include Zip

22-R-0007. Cust Id 170

with USDA

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)WARNER-LAMBERT COMPANY
PHARMACEUTICAL RESEARCH DIV.
201 TABOR ROAD
MORRIS PLAINS, NJ 07950

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

Parke-Davis Pharmaceutical Research Div.
(Now Pfizer Global Research & Development)2800 Plymouth Road
Ann Arbor, MI 48105

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO OF ANIMAL (Cols. C + D + E)
4. Dogs	10	97	127	0	234
5. Cats					
6. Guinea Pigs	0	0	66	0	66
7. Hamsters	0	60	0	0	60
8. Rabbits	0	861	1723	91 E	2675
9. Non-human Primates	42	216	4	42 A, B, C, D	304
10. Sheep					
11. Pigs	0	0	63	0	63
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTER RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SI

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

APHIS FORM 7023
(AUG 91)

(Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 1 - HEADQUARTERS

INFORMATION IN BRACKETS [] IS CONSIDERED
CONFIDENTIAL

DESCRIPTION OF CATEGORY E STUDIES

- A- Five cebus monkeys were sensitized to (b)(4) by repeated dosing and, thus, developed the constellation of side effects, i.e. dyskinesia and extra-pyramidal effects, known to be a liability of many (b)(4). Production of such signs was necessary to determine whether new (b)(4) candidates were free of these effects when given to sensitized monkeys. Distress may have been produced but not pain. These studies were part of a program to develop new pharmaceutical agents and were only used when other non-animal and less invasive studies indicated. All studies were approved by the IACUC and included a search of key words and databases as required by USDA Policy 12. All searches were current and included a substantial review of the scientific literature. The standard operating procedure used to conduct these searches was reviewed by the local USDA veterinarian.
- B- Five cynomolgus monkeys and eight rhesus monkeys were dosed with (b)(4) to create a model of (b)(4). Actual dosing of some of these animals may have occurred prior to fiscal 1999. Pain was not evident but a temporary loss of motor function on the treated site was created. Monkeys were provided complete support as needed. Creating these signs in animals was necessary in order to develop pharmaceutical agents that may be helpful in ameliorating them. These studies were part of a program to develop new pharmaceutical agents and were only used when other non-animal and less invasive studies indicated. All studies were approved by the IACUC and included a search of key words and databases as required by USDA Policy 12. All searches were current and included a substantial review of the scientific literature. The standard operating procedure used to conduct these searches was reviewed by the local USDA veterinarian.
- C- Eighteen squirrel monkeys were used in (b)(4) testing. These animals were exposed to avoidable, short-term electroshock. The shock was (b)(4) to the minimum necessary to achieve (b)(4). These studies were conducted as part of a program to identify new (b)(4) agents. Shock avoidance was the fundamental measurement of the test and, therefore, could not be eliminated only minimized. These studies were part of a program to develop new pharmaceutical agents and were only used when other non-animal and less invasive studies indicated. All studies were approved by the IACUC and included a search of key words and databases as required by USDA Policy 12. All searches were current and included a substantial review of the scientific literature. The standard operating procedure used to conduct these searches was reviewed by the local USDA veterinarian.
- D- A group of six cynomolgus monkeys were used in a model (b)(4). These animals were food deprived (body weights at or above 80% of normal) and subjected to mild electroshock. The shock was the mildest necessary to achieve (b)(4). These studies were conducted as part of a program to identify novel (b)(4) agents. Negative reinforcement was a fundamental component of the test and, therefore, could not be eliminated only minimized. These studies were part of a program to develop new pharmaceutical agents and were only used when other non-animal and less invasive studies indicated. All studies were approved by the IACUC and included a search of key words and databases as required by USDA Policy 12. All searches were current and included a substantial review of the scientific literature. The standard operating procedure used to conduct these searches was reviewed by the local USDA veterinarian.
- E- A group of 91 rabbits were used in a model on (b)(4). These studies may result in mild pain. These studies were conducted to assess efficacy of pharmacological agents in preventing white cell (b)(4), which is a significant cause of cartilage damage in (b)(4). These studies were part of a program to develop new pharmaceutical agents and were only used when other non-animal and less invasive studies indicated. All studies were approved by the IACUC and included a search of key words and databases as required by USDA Policy 12. All searches were current and

11/29/00 WED 17:04 FAX 704 611 7000
included a substantial review of the scientific literature. The standard operating procedure used to conduct these searches was reviewed by the local USDA veterinarian.

EXCEPTIONS TO STANDARDS

1. All 60 hamsters and 1193 rabbits were used on studies of (b)(4) These studies include a diet that although balanced in nutrients contained excesses of fats and cholesterol.
2. Eighteen cynomolgus monkeys were exempted from food enrichment while on an (b)(4) study that required them to eat medicated feed treats.
3. Nine dogs were exempt from the exercise program for veterinary reasons (permanent).
4. Up to 43 dogs were exempted from the exercise program during metabolism studies. These exemptions were generally short term, i.e. 48 hours or less.
5. Four squirrel monkeys and 13 tamarins were exempted from the social housing portion of the psychological well-being program due to either aggressive behavior or lack of same gender partner. Most macaques and cebus monkeys were either exempt from pair housing during at least part of the year by protocol or were incompatible.

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
22-R-0006

FORM APPROVED
OMB NO 0579-0036

2. HE/ incl 22-R-0006. Cust Id 169

Stored with USDX

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

ORTHO PHARMACEUTICAL CORPORATION
ROUTE 202
P.O. BOX 300
RARITAN, NJ 08869

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

R.W. Johnson, PRI Raritan, NJ

R.W. Johnson, PRI Spring House, PA

R.W. Johnson, PRI, LaJolla, CA

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	36	312*	381	53*	746
5. Cats	-	-	-	-	-
6. Guinea Pigs	0	88*	368*	87	543
7. Hamsters	-	-	-	-	-
8. Rabbits	0	143*	432*	6*	581
9. Non-human Primates	20*	51*	37*	15*	103
10. Sheep	-	-	-	-	-
11. Pigs	-	-	-	-	-
12. Other Farm Animals	-	-	-	-	-
13. Other Animals					
Chinchillas	0	0	0	14*	14

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTES RESEARCH FACILITY OFFICIAL (Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 USC Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
		11/30/10

USDA ANNUAL REPORT (1999-2000)**Registration #: 22-R- 0006****Animals Listed in Category E**

During the reporting period, the R.W. Johnson Pharmaceutical Research Institute Institutional Animal Care and Use Committee (IACUC) approved the use of animals in Category E as follows:

SPECIES	NUMBER	PROCEDURE/JUSTIFICATION
Chinchillas	14	(b)(4)
Guinea Pigs	87	
Rabbits	6	
Dogs	1	
Dogs	52	
Non-Human Primates	15	

**** Administration of anesthetics, analgesics or tranquilizing drugs must be withheld so as not to invalidate the evaluation of test compounds.**

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

FORM APPROVED
OMB NO 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA)

22-R-0050. Cust Id 520

SGS U.S. Testing Company, Inc.
291 Fairfield Avenue
Fairfield, NJ 07004

DEC 6 2

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, teaching, testing, surgery, or experimentation, as applicable. Attach additional sheets if necessary.)

es. Attach additional

FACILITY LOCATIONS (Sites)

SGS U.S. Testing Co., Inc.

75 Passaic Ave., Fairfield, NJ 07004

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	N/A				
5. Cats	N/A				
6. Guinea Pigs	0	521	0	750	1271
7. Hamsters	N/A				
8. Rabbits	0	684	6	38	728
9. Non-human Primates	N/A				
10. Sheep	N/A				
11. Pigs	N/A				
12. Other Farm Animals	N/A				
13. Other Animals	N/A				

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 USC Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

11/27/00

KACC

COMMENTS, APHIS FORM 7023

A. The 750 guinea pigs that experienced pain without benefit of analgesics or anesthetic during tests were used in the Kligman Skin Sensitization tests required for the compliance with the Federal Hazardous Substance Act Regulation, the Federal Insecticide, Fungicide and Rodenticide Act regulation and the Toxic Substance Control Act regulation. The concomitant use of analgesic, anesthetic or tranquilizing drugs in these procedures, according to these regulations, would have adversely affected the interpretation of the results.

B. The 38 rabbits that experienced pain without benefit of general analgesics or anesthetics during tests were used in eye and primary skin irritation studies required for the compliance with the Federal Insecticide, Fungicide and Rodenticide Act regulation and the Toxic Substance Control Act regulation. The concomitant use of analgesic, anesthetic or tranquilizing drugs in these procedures, according to these regulations, would have adversely affected the interpretation of the results.

It is the policy of the Toxicology Laboratory to use the minimum number of animals necessary to ascertain hazards associated with chemical insult for any sample tested. The welfare of laboratory animals used in toxicologic studies is an integral part of our laboratory policy. Test substances are flushed from the eye or removed from the skin site as soon as possible without compromising the test protocol. Animals receive local anesthetics, topical antibiotics and the best care available post-testing if chemical insult is minor. The Study Director examines all animals involved in studies where a test article is rated a severe eye or skin irritant. Euthanasia by lethal injection of pentobarbital is performed if an animal is suffering.

C. There were no IACUC-approved exception(s) to the regulations or standards.

By:

11/27/2011
Date